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10/631,980	07/31/2003	Christopher J. Calhoun	MA9604P	2197

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EXAMINER

BETTON, TIMOTHY E

ART UNIT	PAPER NUMBER
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1614

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08/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/631,980

Applicant(s)

CALHOUN ET AL.

Examiner

Timothy E. Betton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3 sheets.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 16 April 2007, have been fully considered but they are not persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant invention.

Status of the Claims

Claims 1-32 are pending. Claims 33-52 are cancelled.

Terminal Disclaimer

Applicants' submission of Terminal Disclaimer filed on 16 April 2007 is acknowledged. The obviousness double patenting rejection directed toward instant claims 1-32 is thereby withdrawn.

Information Disclosure Statement

There are incomplete citations on all three pages under the *other documents* section. These referenced citations have been crossed out pending corrections. Please complete the required information for cited references, i.e., date, page number(s), volume number, etc.

Claim Rejection- 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 11,12, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claims 11,12, and 18 disclose a membrane, which has a glass transition temperature causing the membrane to expand 5 times to 10 times. However, there is nothing in the instant specification or claims, which elucidates claimed invention toward the description and explanation of a glass transition temperature. The instant specification contains no chemical models or structures, which would elucidate the claimed invention. For exemplary purposes, glass transition temperature (T_g) is one of several methods, which make up Differential Scanning Calorimetry. By using the DSC measurements (T_g), one can obtain thermal properties, which can be used to infer polymer structural morphology (Gates, Kimberly, University of Toronto, Controlled Drug Delivery Using Bioerodible Polymeric Systems for the treatment of Periodontitis, (1999), printed pages 188, especially page 41, line 13). Additionally, Gates teaches a detailed graph, which measures and elucidates the endothermic and exothermic heat flow rate of glass transition temperature (page 169, 7.5 Appendix E).

Additionally, the specific additives of instant claim 13 are not elucidated, i.e., specific chemical structures and/ or specific names of agents from the classes of growth factors and cell-migrators.

3Claim Rejection- 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Joint Inventors

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 15-17, and 19-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totakura et al. (USPN 5795584) and Vyarkaram et al (USPN 6333029) in view of Tang et al. (USPN 5412068).

Totakura et al. teach surgical adhesion barriers and methods of using such surgical adhesion barriers. Surgical adhesion barriers according to the present invention have at least one layer of a bioabsorbable material comprising copolymers and/or block copolymers derived from trimethylene carbonate. Alternatively, a multilayer surgical

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structure having one or more bioabsorbable layers superimposed on a non-absorbable layer is useful for minimizing or preventing formation of fibrous adhesions between a healing trauma site and adjacent surrounding tissue. Alternatively, a bioabsorbable non-woven fabric in adherent contact with at least one bioabsorbable layer of foam, film, mesh, web or woven fabric is also provided. One or more medicinal agents may be interposed between or disposed within any of the aforementioned layers (Abstract).

Totokura et al. teach non-porous non-absorbable layered membrane. The disclosure of non-permeability is an essential element, which is also central to claimed invention. Totokura et al. teach lactide and epsilon caprolactone. Further, Totokura et al. teach a viscosity property of 0.9 (instant invention discloses a viscosity property of about 1 g/dL. In Example 4 (column 12, lines 45-6), the inherent viscosity of this polymer is 0.6 to 1.1 dl/g. Additionally, Examples teach thickness ranges of membranes from 1 cm X 2 to 2 cm X 3 cm (columns 11-18). These ranges encompass the ranges disclosed in subject invention.

Totokura et al. does not specifically teach distinctions between membrane layers in terms of differences in mm.

Vyarkarnam et al. teach a three-dimensional inter-connected open cell porous foams that have a gradient in composition and/or microstructure through one or more directions. These foams can be made from a blend of absorbable and biocompatible polymers that are formed into foams having a compositional gradient transitioning from predominately one polymeric material to predominately a second polymeric material.

These gradient foams are particularly well suited to tissue engineering applications and can be designed to mimic tissue transition or interface zones (Abstract).

Vyarkarnam et al. teach a poly-L-lactide, poly-DL-lactide (column 1, lines 39 and 40). Vyarkarnam et al. teach a mole ratio of epsilon caprolactone to p-dioxanone of from about from 30:70 to about 70:30) elastomeric copolymers of p-dioxanone and trimethylene carbonate (preferably having a mole ratio of p-dioxanone to trimethylene carbonate of from about 30:70 to about 70:30), elastomeric copolymers of trimethylene carbonate and glycolide (preferably having a mole ratio of trimethylene carbonate to glycolide of from about 30:70 to about 70:30), elastomeric copolymer of trimethylene carbonate and lactide including L-lactide, D-lactide, blends thereof or lactic acid copolymers (preferably having a mole ratio of trimethylene carbonate to lactide of from about 30:70 to about 70:30) and blends thereof (column 10, lines 60-67). Instant invention is drawn toward a 70:30 poly (L-lactide-co-D,L,-lactide) (pg 5).

Vyarkarnam et al. do not teach non-porous membranes.

Tang et al. teach medical devices formed totally or in part from homopolymers or copolymers comprising recurring carbonate moieties (Abstract).

Tang et al. teach bioresorbable polymers, which are used in the fabrication of devices for implantation in living tissue for several decades. Medical application of such polymers includes absorbable sutures, haemostatic aids and, recently, intraosseous implants and control-release drug delivery systems.

Tang et al. teach descriptions of axes and multilayering of fibers to contain varied concentrations of active agents (column 7). Tang et al teach a viscosity property of 3.0 dL/g. Tang et al teach "shrinking" as disclosed in instant claims 23 and 24 (column 1, lines 50-56).

Claims 6-10, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totakura et al., Vyarkarnam et al., and Tang et al. as applied to claims 1-5, 15-17, and 19-32 above, and further in view of Lemperle et al. (USPN 6391059), Lemperle et al. (USPN 6280473), and Mansmann, K. (USPN 6530956).

Lemperle et al. (059) teach a resorbing flexible implant in the form of a continuous macro-porous sheet (42) is disclosed. The implant is adapted to protect biological tissue defects, especially bone defects in the mammalian skeletal system, from the interposition of adjacent soft tissues during in vitro repair. The membrane (42) has pores with diameters from 20 microns to 3000 microns. This porosity is such that vasculature, and connective tissue cells derived from the adjacent soft tissues including the periosteum, can proliferate through the membrane into the bone defect. The thickness of the sheet is such that the sheet has both sufficient flexibility to allow the sheet to be shaped to conform to the configuration of a skeletal region to be repaired, and sufficient tensile strength to allow the sheet to be so shaped without damage to the sheet. The sheet provides enough inherent mechanical strength to withstand pressure from adjacent musculature, and does not collapse (Abstract).

Lemperle et al. (059) teach a membrane capable of resorbing into the mammalian body within a period of 24 months from the initial implantation (column 6, lines 64-67), which is obvious over instant claim 1.

Lemperle et al. (059) teaches molecular orientation in regard to a single axis or axes (at least two), which is obvious over instant claim 7 of subject invention (column 14, line 1; line 43). Further, Lemperle et al. teach specific additives (column 5, lines 66-67), which is obvious over instant claim 13 of subject invention.

Lemperle et al. (059) does not teach the membrane thickness of about 0.001 mm to about 0.300 mm. Lemperle et al (059) does not teach sealed sterile packaging.

However, Lemperle et al (473) does teach membrane thickness ranges which fall within the instant ranges of 1 micron to 300 microns (column 3, line 62; column 6, lines 9 and 57-60), which is obvious over instant claim 1. Lemperle et al. (473) also teach a range which encompasses instant inventions highest range (column 16, line 9). Lemperle et al. also teach shrinkage of membrane (column 15, line 37).

Additionally, Mansmann, K (USPN 6530956) does teach a resorbable scaffold contained in a sealed sterile package used to help transplanted chondrocytes or other cells generate new cartilage in a damaged joint (column 9, line 15), which is obvious over instant claim 14.

Thus, it would be *prima facie* obvious to one of ordinary skill in the art at the time of invention to recognize with a reasonable expectation of success via the combining and/or incorporating together the methods and compounds of Totokura et al., Vyarkarnam et al., and Tang et al. incorporated with the teachings of Lemperle et al.

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and Mansmann, K. All said references encompass the central elements of claimed invention as explained above. The motivation to combine is present in Totokura et al. which encompasses elements of Vyarkarnam et al. Vyarkarnam et al., in addition, teach elements that are not readily disclosed within Totokura, but encompass further elements obvious over instant claims and subject invention. Tang et al. contains elements of both Totokura et al. and Vyarkarnam et al., but with additional elements that fully encompass elements of claimed invention. Lemperle et al. and Mansmann et al. are the motivation to further combine by encompassing the specific claim limitations of instant claims 6-14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

 5/29/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER